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K023226

510(k) SUMMARY

COMPLETE® brand Multi-Purpose Solution

This summary uses the format provided in 21 CFR 807.92:

(a)(1) **Submitter:**

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Summary Prepared: September 26, 2002

(a)(2) **Device Trade Name:** COMPLETE® brand Multi-Purpose Solution

Device Common Name: Soft (Hydrophilic) Contact Lens Solution

Device Classification/Panel: Class II (Special Controls)/Ophthalmic Device

Device Classification Names: Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:** Reformulated COMPLETE® brand Multi-Purpose Solution is substantially equivalent to the marketed formulations of this product, and to other contact lens multi-purpose solutions.

(a)(4) **Device Description:** Reformulated COMPLETE® brand Multi-Purpose Solution is a sterile, isotonic, buffered, solution containing lubricants, preservatives, buffers, surfactants, ancillary ingredients, and purified water.

The product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use):** Reformulated COMPLETE® brand Multi-Purpose Solution is used for chemical disinfection, cleaning, rinsing, storing, protein removal and conditioning of soft (hydrophilic) contact lenses. These uses are identical to the currently marketed product.

(a)(6) **Comparison of Technological Characteristics:** The technological characteristics of the new formulation remain the same as the current product.

(b)(1) **Discussion of Nonclinical:**

Solution Compatibility and Cleaning Effectiveness: The product was tested using the same protocol used to test the prior (substantially equivalent) formulation. The results show that the product is compatible with, and an effective cleaner for, all soft (hydrophilic) contact lenses.

Clinical Lens Cleanliness: Patient-worn conventional hydrophilic lenses from subjects in the clinical study supporting this application were analyzed for cleanliness and total protein using an objective method. The results support the use of reformulated COMPLETE® in a no-rub regimen for all soft contact lenses replaced at intervals of 90 days or longer.

Passive Protein Cleaning: Reformulated COMPLETE® and a marketed multipurpose solution were tested for their abilities to remove lysozyme protein adsorbed to contact lens surfaces and within the lens matrix. Reformulated COMPLETE® had statistically significant better passive protein cleaning ability than the control.

PHMB Uptake/Release: In testing of preservative (PHMB) uptake and release, reformulated COMPLETE® was substantially equivalent to other marketed multipurpose solutions.

Critical Micelle Concentration of Poloxamer 237: Data provided by the manufacturer of poloxamer 237 shows that the pseudo critical micelle concentration of this surfactant is reached at a concentration >0.01%, well below the amount found in our product (0.05%).

(b)(1) **Discussion of Nonclinical (Continued):**

Microbiological Studies: The product was evaluated for microbiological efficacy using studies outlined in FDA's Premarket Notification [510(k)] Guidance Document for Contact Lens Care Products, issued May 1, 1997, modified to include organic soil in the stand alone test.

- The product meets current FDA requirements for disinfection of contact lenses against bacteria, yeast and mold.
- The product meets the USP Modified criteria for Preservative Effectiveness Testing.
- The product meets USP Sterility test requirements.

Stability: Accelerated testing predicts that the product will remain stable for the labeled shelf-life.

Toxicology: The safety of reformulated COMPLETE® was evaluated with best and worst case formulations using the following tests:

- Cytotoxicity: Neither the test formulations, nor the control, were cytotoxic to mouse fibroblast cells after 24 hours.
- Sensitization: There were no dermal reactions from either test or control.
- Acute Oral Toxicity: Neither test formulation caused an adverse effect when administered to rats in a single oral dose.
- 22-Day Ocular Safety Studies: Treatment with either of the two test formulations or control was well tolerated in rabbits.

(b)(2) **Discussion of Clinical Data:**

AMO conducted a multi-center, investigator-masked, randomized, parallel-group, three-month evaluation to assess the safety and acceptability of reformulated COMPLETE® brand Multi-Purpose Solution. The results of this study indicate that the investigational formulation is safe, acceptable, and substantially equivalent to the control.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determination:** It is concluded that the safety, efficacy and performance of reformulated COMPLETE® brand Multi-Purpose Solution is substantially equivalent to the predicate products currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Advanced Medical Optics, Inc.
c/o Mr. Paul J. Nowacki
Manager, Regulatory Affairs
1700 E. St. Andrew Place
P.O. Box 25162
Santa Anna, CA 92799-5162

Re: K023226
Trade/Device Name: COMPLETE® brand Multi-Purpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated: September 26, 2002
Received: September 27, 2002

Dear Mr. Nowacki:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER:
(IF KNOWN): K023226

DEVICE NAME: COMPLETE® brand Multi-Purpose Solution

INDICATIONS FOR USE:

COMPLETE® brand Multi-Purpose Solution is indicated for the care of soft (hydrophilic) contact lenses. Use this product, as recommended by your eye care practitioner, to:

- Chemically (NOT HEAT) Disinfect
- Clean
- Rinse
- Store
- Remove Protein
- Condition

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K023226

Over-the-Counter Use ✓

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter-Use X
(Per 21 CFR 801.109 (Optional Format 1-2-96)